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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,541	03/17/2004	Gary Brodsky	2848-53	6260

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EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/803,541	BRODSKY, GARY	
	Examiner	Art Unit	
	Anand U. Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to an isolated peptide selected from the group consisting of a peptide comprising SEQ ID NO: 2, a biological active fragment of SEQ ID NO: 2, and a peptide that has 70% identity to SEQ ID NO: 2, and has the biological activity of SEQ ID NO: 2, and a therapeutic composition comprising the isolated peptide and a pharmaceutical acceptable carrier, classified in class 530, subclass 300, and class 424, subclass 185.1.

II. Claims 9-12, drawn to an isolated nucleic acid molecule selected from the group consisting of a nucleic acid sequence encoding an amino acid sequence comprising SEQ ID NO: 2, encoding a fragment of SEQ ID NO: 2, having the biological activity of SEQ ID NO: 2, encoding a peptide that has 70% identity to SEQ ID NO: 2, and has the biological activity of SEQ ID NO: 2, encoding a peptide that differs from SEQ ID NO: 2 by at least one substitution, deletion, or insertion, and wherein the peptide has the biological activity of SEQ ID NO: 2, and nucleic acid sequence that is fully complementary to any of the above sequences, classified in class 435, subclass 69.1, 320.1, class 536, subclass 23.5, 24.1, and 24.5.

III. Claim 13, drawn to a recombinant nucleic acid molecule comprising a nucleic acid sequence operatively linked to a recombinant expression vector for gene delivery selected from the group consisting of a nucleic acid sequence encoding

SEQ ID NO: 4, a biologically active fragment of SEQ ID NO: 4, and a nucleic acid sequence encoding an amino acid that has 70% identity to SEQ ID NO: 4, wherein the amino acid sequence has prelamin A or lamin A biological activity, classified in class 536, subclass 23.1.

IV. Claim 14, drawn to a therapeutic protein comprising a protein selected from the group consisting of a protein comprising amino acid sequence represented by SEQ ID NO: 4, a biologically active fragment of SEQ ID NO: 4, and a protein comprising an amino acid sequence that has 70% identity to SEQ ID NO: 4, and has prelamin A or lamin A biological activity, wherein the protein is attached to a therapeutic agent that increase the half-life of the protein in cardiac or skeletal muscle tissue, classified in class 424, subclass 193.1.

V. Claims 15, and 16, drawn to a carrier for therapeutic agents and a therapeutic composition comprising an isolated peptide, classified in class 530, subclass 300.

VI. Claim 17, drawn to a recombinant nucleic acid molecule encoding a carrier operatively linked to a nucleic acid sequence encoding a protein for the promotion of myoblast activation and growth or regeneration of cardiac or skeletal muscle, classified in class 536, subclass 23.1.

VII. Claims 18-22, drawn to a method to identify compounds that modulate the activity of prelamin A protein or prelamin A peptide, classified in class 435, subclass 70.1.

VIII. Claim 23, drawn to a method to identify compounds that bind prelamin A protein or prelamin A prepeptide, classified in class 530, subclass 387.1.

IX. Claims 24-29, drawn to a method to identify compounds that regulate an activity in a cell selected from the group consisting of prelamin A processing, prelamin A prepeptide transport, and myoblast activation or differentiation, classified in class 435, subclass 375.

X. Claims 30 and 31, drawn to a method to identify human genes that regulate myoblast activation and differentiation, classified in class 435, subclass 6.

XI. Claims 32-37, drawn to a method to identify an inhibitor of prelamin A farnesylation, classified in class 435, subclass 325.

XII. Claims 38-40, drawn to a processing deficient prelamin A peptide, classified in class 514, subclass 722.

XIII. Claim 41, drawn to an isolated cell transfected with a processing deficient prelamin A peptide, classified in class 424, subclass 93.2.

XIV. Claims 42 and 43, drawn to a method to promote myoblast activation and regeneration of damaged, degenerated or atrophied cardiac and skeletal myocytes, and a method to stimulate cardiac or skeletal muscle growth in a mammal, comprising administering the isolated peptide of claim 1 or a composition comprising the peptide, classified in class 435, subclass 377.

XV. Claims 44 and 45, drawn to a method to treat cardiac and skeletal muscle disorders comprising administering the therapeutic peptide disclosed in claim 14 drawn to SEQ ID NO: 4, classified in class 424, subclass 9.2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II, III, IV, V, VI, XII, and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different structures and modes of operation. The polypeptides of groups I, IV, V, XII, the polynucleotides of groups II, III, VI, and the isolated transfected cell of group XIII are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. The isolated cell of group XIII is a structurally distinct composition. In the present claims, a polynucleotide of group II does not necessarily encode a polypeptide of group I. For example, as disclosed in the specification, SEQ ID NO: 2 is 15 amino acids in length, whereas the nucleic acid molecule of claim 9(e) is complementary to the coding sequence, and therefore would not encode the polypeptide of group I. Furthermore, the information provided by the polynucleotide of group II can be used to make a materially different polypeptide than that of group I. For example, a nucleic acid which hybridizes to SEQ ID NO: 1, even under stringent conditions, encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with SEQ ID NO: 2. For these reasons, the inventions of groups I and II are patentably distinct.

Furthermore, searching the inventions of groups together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides, which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers that had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. In addition, the polypeptide claims include polypeptides having 70% identity to the sequence identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above; furthermore, a search of the nucleic acid molecules of claim 9(c) would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group I. As such, it would be burdensome to search the inventions of the groups together.

The polypeptides of groups I, IV, V, and XII are structurally distinct molecules. The polynucleotide sequences of groups II, III, and VI are structurally distinct molecules. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. Similarly, an amino acid sequence search for residues for 1-11 is required to determine the novelty and nonobvious of the peptide of group I, however such a search is not required or sufficient to identify all of the polypeptides of group IV. Thus,

searching the inventions of groups I, IV, V, and XII or groups II, III, and VI would impose a serious search burden. In addition, the technical literature searches for the polypeptides of the groups or the polynucleotides of the groups are not coextensive.

3. Inventions VII, VIII, IX, X, XI, XIV, and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The methods are all unrelated, as they comprise distinct steps and utilize different products, which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. For these reasons the Inventions are patentably distinct. Furthermore, the distinct steps and products require separate and distinct searches. The inventions of groups VII, VIII, IX, X, XI, XIV, and XV have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of groups VII, VIII, IX, X, XI, XIV, and XV together.

4. Inventions I, IV, V, XII and XIV, XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated peptides of groups I, IV, V, XII, and XII can be used to immunize an animal to make antibodies as opposed to its use in treating cardiac and skeletal disorders.

Searching the inventions of groups I, IV, V, XII, XIV, and XV together would impose serious search burden. The inventions of groups I, IV, V, XII, XIV, and XV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the peptide and the methods of using are not coextensive. Prior art that teaches a polypeptide, which is 70% identical to SEQ ID NO: 2 would not necessarily be applicable to the method of using the polypeptide comprising SEQ ID NO: 2. Moreover, even if the polypeptide product were known, the method of treatment that uses the product may be novel and unobvious in view of the preamble or active steps.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

June 17, 2005